Policy for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

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Policy for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

II. Policy

A. Policy Statement

The University of Texas at Arlington (UTA) is committed to safe practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

Activities involving recombinant or synthetic nucleic acid molecules will be evaluated and conducted in accordance with the National Institutes of Health (*NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, effective April 2016 and all subsequent amendments.

B. Scope

As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, UTA shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the NIH Guidelines.

These policies are applicable to all activities which, in whole or in part, involve research with recombinant or synthetic nucleic acid molecules and occur in university facilities as well as other locations whenever projects involve university funding, faculty scholarship, or any faculty/staff/student effort as part of university activities.

C. Policy Standards

1. The Vice President for Research is assigned the role of Institutional Official (IO) with overall responsibility for ensuring the proper use of recombinant or synthetic nucleic acid molecules and compliance with the NIH Guidelines.

2. An Institutional Biosafety Committee (IBC) will be maintained to review projects and activities that involve recombinant or synthetic nucleic acid molecules in accordance with the NIH Guidelines. IBC membership shall comply with the requirements of the NIH Guidelines and include the expertise necessary to evaluate the use and containment of recombinant or synthetic nucleic acid molecules. Formal membership appointments will be made by the Institutional Official.

   Investigators, including those that may serve as IBC members, may not participate in the initial review, continuing review, modification review, or any other review of any project in which the Investigator has a conflict of interest. When an investigator has a conflicting interest, he or she may be present at IBC meetings only to provide information requested by the committee. The conflicted investigator cannot participate in voting activity for that project

3. No activity involving recombinant or synthetic nucleic acid molecules shall take place until review and preapproval of such activity by the IBC.

4. The conduct of any research involving recombinant or synthetic nucleic acid molecules shall be reviewed by the IBC before it is begun and periodically thereafter in accordance with the NIH Guidelines. The frequency of continuing review will be determined by the IBC based on its discretion, taking into consideration their risk assessment of the experiments. The determined frequency will be communicated to the investigator in writing at the time of approval. Research covered by this policy that has been approved by the IBC may be subject to further appropriate review and approval or disapproval by officials of the institution (for example, certain projects

may expose the institution to risk or liability or involve other procedures that may require administrative review and approval).

5. The IBC has the authority to review and approve, require modifications in (to secure approval), or withhold approval of proposed activities involving recombinant or synthetic nucleic acid molecules. The IBC has authority to suspend or terminate protocol approval for recombinant/synthetic nucleic acid research where the IBC finds non-compliance, or when such use or possession poses a threat to the health and safety of the community.

6. The IBC shall coordinate as appropriate with UTA's Institutional Review Board for the Protection of Human Subjects (IRB), the Institutional Animal Care & Use Committee (IACUC), the Research Conflict of Interest Committee (RCOIC) and the Radiation Safety Committee (RSC).

7. Reviews by the IBC will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of the members. Members will be excluded from review of projects or activities in which they have an active role or conflict of interest, in accordance with related federal regulations and UTA Policy RA-PO-02. When possible and consistent with protection of privacy and proprietary interests, IBC meetings shall be open to the public.

8. In cooperative research projects (those projects normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to UTA), each institution is responsible for complying with the NIH Guidelines as applicable. When research is conducted at or in cooperation with another entity, the investigator must obtain either approval from the UTA IBC, or written acknowledgement from the UTA IBC of its acceptance of a collaborating institution's IBC approval for the project.

9. Investigators working with recombinant or synthetic nucleic acid molecules must adhere to the standard operating procedures (SOP's) of the IBC. See Section V.

D. Records

Upon request, the institution shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies in accordance with the Texas Public Information Act.

Records will be maintained in accordance with federal and state regulations and UTA's policies and procedures for records and information management and retention located in UTA Policy GA-LA-PO-02. Records

will include research protocols, related correspondence, IBC actions, and meeting minutes. Records are maintained by the Office of Regulatory Services.

III. Definitions

Institutional Biosafety Committee (IBC): Is the committee appointed by the University's Institutional Official charged with providing local review and oversight of activities utilizing recombinant or synthetic nucleic acid molecules.

Institutional Official (IO): Is the individual who, as a representative of senior administration, bears ultimate responsibility for the program and is responsible for resource planning and ensuring alignment of program goals with UTA's strategic plan. The IO is the Vice President for Research.

Recombinant and Synthetic Nucleic Acid Molecules: Are defined as (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above.

IV. Relevant Federal and State Statutes

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

V. Relevant UT System Policies, Procedures and Forms

UTA Policy GA-LA-PO-02 *Records Management and Retention*

UTA Policy RA-PO-02 *Policy for Disclosure, Management, and Reporting of Conflicts of Interest in Research*

Institutional Biosafety Committee (IBC) Standard Operating Procedures

Environmental Health & Safety Office Biological Standard Operating Procedures

UTA Biosafety Manual

VI. Who Should Know

All UTA employees and students engaging in research.

VII. UTA Office(s) Responsible for Policy

Responsible Officer: The Vice President for Research

VIII. Dates Approved or Amended

August 27, 2020

IX. Contact Information

All questions concerning this policy should be directed to Research Administration – Office of Regulatory Services at regulatoryservices@uta.edu or www.uta.edu/uta/research, 817-272-3723.

Send notifications of errors or changes to: policysite@uta.edu